

REMARKS

Claims 11-29 are pending stand rejected under 35 U.S.C. §§ 102 and 103.

Applicants note with appreciation that claims 1-7 and 10 are considered allowable and that claim 22 would be allowable if rewritten independent form.

Claim 11 has been amended herein to make explicit that the plasmid encoding the viral immunogen contains a single control sequence that drives expression of the immunogen and that this single control sequence is derived from a virus. Support for this amendment can be found throughout the specification as filed, for instance in the Examples which disclose the use of plasmids containing a CMV promoter/enhancer sequence. In addition, new claims 30 and 31 have been added. New claim 30 is drawn to the subject matter of original claim 22, which the Examiner indicates would be allowable in independent form. Support for new claim 31 can be found throughout the specification as filed, for example on page 5, line 30 to page 6, line 9 and in original claims 14, 15, 18 and 19. No new matter has been added as a result of these amendments and entry thereof is respectfully requested.

In view of the foregoing amendments and following remarks, Applicant respectfully requests reconsideration of the application.

35 U.S.C. § 102(e)

Claims 11-13, 16, 17, 21, 25 and 27-29 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by U.S. Patent No. 5,846,546 (hereinafter "Hurwitz"). (Final Office Action, page 2). Claims 11-13, 16, 17, 21, 23-29 stand rejected as allegedly anticipated by U.S. Patent No. 6,355,247 (hereinafter "Selby"). (Final Office Action, page 3). Hurwitz is cited for allegedly disclosing a method involving administration of a chemokine and a DNA immunogen carried on a bifunctional plasmid. (Final Office Action, page 3). Selby is cited for allegedly disclosing the use of plasmids as well as viral vectors. (Final Office Action, page 3).

Because neither Hurwitz nor Selby disclose each and every element of the pending claims, Applicant traverses the rejections and supporting remarks.

Pending claims 11-29 are directed to methods in which the immunogen is administered as a plasmid. Furthermore, expression of the immunogen included in this plasmid is controlled by a single expression control sequence derived from a virus. In contrast, Hurwitz discloses only the use of bi-functional plasmids, *i.e.*, plasmids that contain at least two expression control elements. Indeed, Hurwitz plainly teaches that his plasmids must be bi-functional in order "serve as a DNA vaccine and a recombinant virus vector..." (Hurwitz, col. 4, lines 43-45). With regard to new claims 30 and 31, it is acknowledged that Hurwitz fails to teach or suggest methods in which a plasmid encoding an immunogen and BLC are administered (claim 30) and methods in which the

plasmid and chemokine (or plasmid encoding a chemokine) are administered successively (claim 31). Thus, Hurwitz does not teach or suggest any of methods as claimed.

For its part, Selby requires that the vector containing the antigen include a T7 RNA promoter derived from bacteriophage. Thus, Selby's vectors either contain more than one control sequence or, alternatively, contain a single control sequence that is not derived from a virus. In either case, Selby cannot anticipate pending claims 11-29. Furthermore, for the reasons noted above with regard to Hurwitz, Selby does not anticipate new claims 30 and 31.

Since there is not identity between the methods of the pending claims 11-31 and the disclosures of Hurwitz and Selby, anticipation cannot be established. Accordingly, withdrawal of the rejections based on 35 U.S.C. § 102 is respectfully requested.

35 U.S.C. § 103

Claims 11-21 and 23-29 stand rejected as allegedly obvious over Hurwitz in view of U.S. Patent No. 6,214,540 (hereinafter "DeVico"). (Final Office Action, page 4). Claims 11-13, 16, 17, 21, 27, and 29 stand rejected as allegedly obvious over U.S. Patent No. 6,383,774 (hereinafter "Chandrashekar") in view of Hurwitz. (Final Office Action, pages 4-5). Hurwitz is cited as above. DeVico is cited for teaching the use of chemokines for HIV therapy using chemokines and Chandrashekar is cited for teaching plasmids containing immunogens derived from parasites. (Final Office Action, page 5).

There is no combination of cited references that renders the pending claims obvious. Nowhere do Hurwitz, Chandrashekar or DeVico describe or suggest methods using plasmids containing a single promoter derived from a virus; methods in which a plasmid encoding an immunogen and BLC are administered; or methods in which a chemokine (or polynucleotide encoding a chemokine) and plasmid encoding an immunogen are administered successively in either order. Indeed, as noted above, Hurwitz fails to suggest the use of plasmids having a single virally derived promoter/enhancer sequence that drives expression of immunogen. Thus combining Hurwitz with Chandrashekar or DeVico would result, at best, in a bifunctional plasmid that includes sequences encoding either an immunogen derived from a parasite (Chandrashekar) or a chemokine (DeVico). Methods involving bifunctional plasmids are entirely different from those claimed by Applicants. Furthermore, as acknowledged by the Office, there is no combination of Hurwitz, DeVico and Chandrashekar that renders claims 30 and 31 obvious.

Accordingly, because there is no teaching or suggestion within the references to arrive at any of the claimed subject matter, withdrawal of the rejections is respectfully requested.

CONCLUSION

For the reasons state above, Applicant respectfully submits that the pending claims define an invention that is novel, non-obvious, fully enabled and described by the specification. Accordingly, Applicant requests that the rejection of the claims be withdrawn, and that the application proceed to allowance.

Please direct all further communications regarding this application to:

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